No. 06-1291

FILED
APR 25 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

In The

Supreme Court of the United States

AMGEN INC.,

Petitioner,

v.

HOECHST MARION ROUSSEL, INC. (now known as AVENTIS PHARMACEUTICALS INC.) and TRANSKARYOTIC THERAPIES, INC. (now known as SHIRE HUMAN GENETIC THERAPIES, INC.),

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF *AMICUS CURIAE* OF THE SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PETITIONER

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I. THE INTEREST OF THE *AMICUS CURIAE*[1]

The *Amicus Curiae*, the San Diego Intellectual Property Law Association ("SDIPLA"), is a non-profit organization comprising a representative cross-section of individuals in San Diego County with an interest in intellectual property law. Its membership is drawn from patent attorneys and agents who address patent issues on behalf of companies, institutions, and inventors. SDIPLA members represent both owners and users of intellectual property. The San Diego region is home to a significant share of the nation's telecommunications, biotechnology and pharmaceutical companies, and a number of research institutions, including the University of California at San Diego, Salk, Scripps, and the Burnham Institute.

A 2004 study ranked San Diego first among U.S. biotechnology centers, based on two broad categories: the innovation pipeline (the infrastructure that allows a region to capitalize on its biotech knowledge and creativity) and the current impact assessment (an area's success in bringing ideas to the marketplace and creating companies, jobs and products). *See* Skip Rimer, *Study Ranks San Diego #1 Among U.S. Biotech Centers*, Biotechnology News, June 17, 2004, at I-2.

The SDIPLA has no stake in any of the parties to this litigation or the result of this case, other than its interest in seeking correct and consistent interpretation of the law affecting intellectual property and the enforcement and defense of intellectual property rights.

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[1] No counsel for any party authored this brief either in whole or in part, and no persons other than the *Amicus Curiae* and its counsel made any monetary contribution to its preparation or submission. The parties' written consents to the filing of this brief have been filed with the Clerk of the Court.

II. SUMMARY OF ARGUMENT

The SDIPLA respectfully submits this brief in support of petitioner, Amgen Inc., urging the grant of a petition for writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit. The Federal Circuit's judgment fails to give appropriate deference to the trial court's evidentiary findings underlying its legal conclusions on claim construction and the application of prosecution history estoppel to the Doctrine of Equivalents, and additionally fails to apply the appropriate test under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), for determining whether the patentee rebutted the presumption of surrender of equivalents.

The interest of the *Amicus* is in ensuring that the appellate standard of review for factual findings underlying claim construction properly allocates judicial resources, and appropriately weighs the public interest in certainty in patent practice that would be promoted if the Court of Appeals accorded deference to the trial court as the finder of the facts. To continue *de novo* review of these factual findings will perpetuate a high reversal rate; tend to undermine the legitimacy of the district courts in the eyes of patent litigants, multiply appeals by encouraging appellate retrial of factual issues, delay settlements until appellate resolution, and needlessly duplicate and reallocate judicial authority. The Court's guidance is therefore needed to ensure that the trial on the merits is the "main event," not just a "tryout on the road" to the Federal Circuit. *See Wainwright v. Sykes*, 433 U.S. 72, 90 (1977).

The Federal Circuit's unwillingness to acknowledge the evidentiary underpinnings of claim construction have also forced trial courts to disclaim reliance on extrinsic evidence that could inform the court's understanding of the meaning of technical terms to one of ordinary skill in the art. In view of these difficulties with the Federal

Circuit's *de novo* review standard, the SDIPLA therefore urges the granting of *certiorari* and a holding that the District Court should find facts necessary for claim construction.

A further interest of the SDIPLA is to preserve the flexibility of this Court's rule governing rebuttal of the presumption of surrender of equivalents under *Festo*. This Court has previously determined that advancing appropriate incentives for innovation warrants application of a "flexible rule" to determine if a patentee has rebutted the presumption of surrender of equivalents. Additional direction from this Court on the proper formulation of the "tangential relation" test, and whether appellate review includes deference to underlying factual findings is thus necessary to prevent resurrection of a rigid bar to infringement under the doctrine of equivalents.

The Court's decision whether to grant *certiorari* will therefore have far ranging effects on appellate review of trial court rulings in patent cases, and in ensuring appropriate incentives for innovation.

III. ARGUMENT

A. THE FEDERAL CIRCUIT'S *DE NOVO* REVIEW OF THE EVIDENTIARY UNDERPINNINGS OF CLAIM CONSTRUCTION SHOULD BE OVERRULED

At issue in this case is the standard of review of factual findings underlying patent claim construction. *See Markman v. Westview Instruments Inc.*, 517 U.S. 370 (1996).

This Court's lodestar ruling in *Markman* has indelibly altered the course of patent litigation. Yet, in the decade since this Court pronounced that the trial court is the

proper arbiter of claim construction, the Federal Circuit has wrestled with its standard of review for fact findings underlying claim construction, and further, the extent to which the trial court may base its claim construction on extrinsic evidence. *See, e.g., Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448 (Fed. Cir. 1998); *see also id.* at 1462 (Plager, J., concurring); *id.* at 1464 (Mayer, C.J., and Newman, J., concurring); *id.* at 1473-75 (Rader, J., dissenting in part); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1040-41 (Fed. Cir. 2006) (denying *reh'g en banc*) ("*Amgen V*") (Michel, C.J., and Rader, J., dissenting); *id.* at 1043 (Newman, J., dissenting); *id.* at 1044 (Rader, J., dissenting); *id.* at 1046 (Moore, J., dissenting). Even though the *en banc* panel of the Federal Circuit settled on *de novo* review in *Cybor*, the debate has continued. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (noting the order granting rehearing *en banc* requested parties to brief the issue of whether to accord deference to any aspect of trial court claim construction rulings, but deciding not to address the issue).

Because claim construction is the first step in the analysis of patent infringement and invalidity, claim construction is the centerpiece for any patent litigation. Indeed, this Court has recognized that victory in a patent lawsuit turns on whether a patent claim covers "the alleged infringer's product or process," which requires a determination of "what the words in the claim mean." *Markman*, 517 U.S. at 374 (quoting H. Schwartz, Patent Law and Practice 80 (2d ed. 1995)).

Litigants and trial courts undertaking the odyssey of determining claim construction from the vantage of one of ordinary skill in the art, however, are caught between the Scylla of resorting to expert testimony and other extrinsic evidence to inform the court of the meaning of claim terms to one of ordinary skill in the art, and the Charybdis of the Federal Circuit's *de novo* review, and Spartan view of

circumstances when reliance on extrinsic evidence is proper. *E.g.*, *Phillips*, 415 F.3d at 1330 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons."); *see also Amgen V*, 469 F.3d at 1040-41 (Michel, C.J., and Rader, J., dissenting) ("It seems to me that the claim construction question often cannot be answered without assessing . . . what the average artisan knew and how she thought about the particular technology when the patent claims were written . . . Indeed, trial judges are arguably better equipped than appellate judges to make these factual determinations"); *Cybor*, 138 F.3d at 1476 (Rader, J., dissenting) (noting the Federal Circuit's high reversal rate, attributed to that court's free review of claim construction).

In the eight years following *Markman*'s allocation of claim construction to the court, the Federal Circuit held that the district court erred in construing 34.5% of claim terms. *See* Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?* 9 LEWIS & CLARK L. REV. 231, 239 (2005) (evaluating cases from 1996-2003). That reversal rate rose further after *Cybor*'s ruling that even "allegedly fact based questions relating to claim construction" were to be reviewed *de novo*. *See id.* at 246.

Thus, clarification by this Court that the standard for appellate review of a trial court's claim construction should require deference to underlying evidentiary findings will provide greater certainty in patent practice, promote greater confidence in the court system and properly allocate judicial resources.

1. This Court Has Recognized that Claim Construction Is Based on Factual Underpinnings

Although this Court ruled in *Markman* that the trial court judge's trained ability to evaluate expert testimony in relation to the overall structure of the patent outweighed the jury's forte in determining witness credibility, it reached its decision to cede claim construction to the judge "notwithstanding its evidentiary underpinnings." *Markman*, 517 U.S. at 390.[2] The Court further explained that the "mongrel" issue of construing a term of art following receipt of evidence did not lend itself to a simple line drawing between "issues of fact and law." *Id.* at 378. Instead, the Court looked to whether the judge or the jury was best suited to address the mixed issue of claim construction, falling somewhere between a "pristine legal standard and simple historical fact." *Id.* at 388 ("[J]udges, not juries, are better suited to find the acquired meaning of patent terms.").

2. The Facts Underlying Claim Construction Should Be Reviewed with Deference

Despite the Court's recurring characterization of claim construction as a mixed issue of law and fact, the Federal Circuit held that *Markman* did not compel deferential appellate review of factual findings underlying claim interpretations, concluding instead that "[n]othing in the

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[2] The Court also noted that allocating claim construction to the court would promote intrajurisdictional certainty; however, even different panels of the Federal Circuit have reached different claim constructions on different records. *See CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1157-58, 1160 n.7 (Fed. Cir. 1997) (finding error in claim construction affirmed in an earlier appeal from ruling on motion for preliminary injunction), *cert. denied*, 118 S.Ct. 1039 (1998).

Supreme Court's opinion supports the view . . . that claim construction may involve subsidiary or underlying questions of fact." *Cybor*, 138 F.3d at 1455. By relegating the Court's characterizations of claim construction to the status of "prefatory comments" and holding that claim construction was "purely legal," the *Cybor en banc* panel sidestepped reconciling its *de novo* standard of review with Federal Rule of Civil Procedure 52(a)'s mandate that factual findings be reviewed under a "clearly erroneous" standard, and further failed to accommodate "the respective institutional advantages of trial and appellate courts." *See, e.g., Anderson v. City of Bessemer*, 470 U.S. 564, 574-75 (1985) (Rule 52(a) requires fact findings to be reviewed with deference); *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991) ("Those circumstances in which Congress or this Court has articulated a standard of deference for appellate review of district-court determinations reflect an accommodation of the respective advantages of trial and appellate courts."). The ruling in *Cybor* also ignores inconsistencies that could result if the level of ordinary skill in the art is reviewed *de novo* for claim construction, but with deference for other patent law issues.

(a) Federal Rule of Civil Procedure 52(a) Mandates that Trial Court Factual Findings Be Reviewed with Deference

This Court has staunchly held that deferential review of trial court factual findings pursuant to Federal Rule of Civil Procedure 52(a) is the rule, rather than exception. *E.g., Anderson*, 470 U.S. at 574-75; *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844 (1982); *cf. Bose Corp. v. Consumers Union*, 466 U.S. 485 (1984) (holding that compelling constitutional concerns and line of First Amendment Supreme Court case law warranted finding exception for standard of review of "malice").

"To permit courts of appeals to share more actively in the fact-finding function would tend to undermine the legitimacy of the district courts in the eyes of litigants, multiply appeals by encouraging appellate retrial of some factual issues, and needlessly reallocate judicial authority." Fed. R. Civ. P. 52(a), Advisory Committee Notes to the 1985 Amendment (discussing justification for deferential review of factual findings, including those based on documentary evidence). Deferential review of fact findings avoids duplication and "diversion of judicial resources" even when the factual findings are not based on determinations of credibility. *See Anderson*, 470 U.S. at 574-75. The conclusiveness of a finding of fact, however, depends on the nature of the evidence supporting the finding and whether the fact is a historical fact or ultimate fact; for example, fact findings based on determinations of witness credibility may be entitled to a greater presumption of deference under Rule 52(a). *Bose Corp.*, 466 U.S. at 500-01 & n.16. The deference accorded fact findings may further depend on the length and complexity of the trial court proceeding:

> [T]he standard does not change as the trial becomes longer and more complex, but the likelihood that the appellate court will rely on the presumption tends to increase when trial judges have lived with the controversy for weeks or months instead of just a few hours.

Id. at 500.

Consistent with these principles, several judges writing separately to concur in the majority opinion in *Cybor* supported deferential review of the trial court's fact findings. *See, e.g., Cybor*, 138 F.3d at 1462 (Plager, J., concurring) ("Though we review that record 'de novo,' meaning without applying a formally deferential standard of review, common sense dictates that the trial judge's view will carry weight. That weight may vary depending on the care, as shown in the record, with which that view

was developed, and the information on which it was based."); *id.* at 1463 (Bryson, J., concurring) ("Simply because a particular issue is denominated a question of law does not mean that the reviewing court will attach no weight to the conclusion reached by the tribunal it reviews . . . What it means is that we approach the legal issue of claim construction recognizing that with respect to certain aspects of the task, the district court may be better situated than we are, and that as to those aspects we should be cautious about substituting our judgment for that of the district court."); *id.* at 1464 (Mayer, C.J., and Newman, J., concurring) ("Wisely, the Supreme Court stopped short of authorizing us to find facts *de novo* when evidentiary disputes exist as part of the construction of a patent claim and the district court has made these findings without committing clear error."). Unlike statutory construction, the facts underlying the interpretation of a patent relate to the level of skill in the technology and the understanding of one of skill in the art. *See, e.g.*, *Amgen V*, 469 F.3d at 1040-41 (Michel, C.J., and Rader, J., dissenting). Accordingly, the factual findings relevant to claim construction should be reviewed with deference, in accordance with the principles underlying Rule 52(a).

(b) The Trial Court Is Better Positioned to Make Factual Findings on Claim Construction

This Court has further advised that the respective advantages of trial and appellate court determinations should be weighed in determining whether the appellate court should defer to a trial court's factual findings:

> The Court counsels appellate courts to defer "when it appears that the district court is 'better positioned' than the appellate court to decide the issue in question or that probing appellate scrutiny will not contribute to the clarity of legal doctrine."

> *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991). At another point, the Court cautions: "[T]he reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts.'" *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 948 (1995) (quoting *Salve Regina*, 499 U.S. at 233).

Cybor, 138 F.3d at 1477 (Rader, J., dissenting from the pronouncements on claim interpretation); *see also Amgen V*, 469 F.3d at 1040-41 (Michel, C.J., and Rader, J., dissenting) (noting that trial judges are arguably better equipped than appellate judges to make fact findings related to claim construction). The trial court in a patent proceeding is better positioned than the Federal Circuit to acquire and evaluate testimonial evidence, and has more time to devote to review of documentary evidence pertinent to claim construction:

> Trial judges can spend hundreds of hours reading and rereading all kinds of source material, receiving tutorials on technology from leading scientists, formally questioning technical experts and testing their understanding against that of various experts, examining on site the operation of the principles of the claimed invention, and deliberating over the meaning of the claim language. If district judges are not satisfied with the proofs proffered by the parties, they are not bound to a prepared record but may compel additional presentations or even employ their own court-appointed expert.

Cybor, 138 F.3d at 1477 (Rader, J., dissenting). Finally, it is unfair to litigants to force them to retry underlying facts to an appellate court ill-suited to acquire factual evidence:

> In addition, the parties to a case on appeal have already been forced to concentrate their energies and resources on persuading the trial judge that

> their account of the facts is the correct one; requiring them to persuade three more judges at the appellate level is requiring too much. As the Court has stated in a different context, the trial on the merits should be "the 'main event' . . . rather than a 'tryout on the road.'" *Wainwright v. Sykes*, 433 U.S. 72, 90, 97 S.Ct. 2497, 2508, 53 L.Ed.2d 594 (1977).

Bose Corp., 466 U.S. at 485; *see also Cybor*, 138 F.3d at 1466 (Mayer, C.J., and Newman, J., concurring) ("[T]hen the absence of review as a matter of right over *our* claim constructions, which may be new and unsupported by legal analysis, or may never have been tested by the adversarial process, would transform this court into a trial court of first and usually last resort.").

(c) Deferential Review of Factual Findings Underlying Claim Construction Will Promote Consistency

Deferential review is also required to avoid inconsistent appellate rulings on the same or similar fact findings underlying multiple patent law determinations. For example, when the determination of the level of skill in the art underlies the legal conclusions of obviousness and enablement, it is reviewed with deference. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (obviousness is a question of law with underlying factual inquiries including the level of ordinary skill in the art); *Enzo Biochem Inc. v. Calgene Inc.*, 188 F.3d 1362 (Fed. Cir. 1999) (factual determination of skill of those in the art underlying the legal conclusion of enablement is reviewed for clear error).[3]

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[3] Fact findings underlying legal conclusions for several other patent issues are reviewed with deference. *E.g., Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1985) (anticipation is a question of fact, reviewed for clear error), *U.S. Envtl. Prods., Inc. v. Westall*, 911 F.2d 713, 715 (Fed. Cir. 1990) (facts underlying conclusion

(Continued on following page)

Thus, inconsistent rulings may result if a determination of the level of skill in the art is reviewed *de novo* for purposes of claim construction but reviewed for clear error for purposes of invalidity.

3. The Federal Circuit Failed to Give Deference to Factual Findings of the Trial Court Based on Lengthy Testimony on Complex Technology

The factual findings that underlie claim construction include the level of ordinary skill in the art at the time of filing; the background of the technology; and the customary meaning of technical claim terms to one of ordinary skill in the art. *See, e.g., Phillips*, 415 F.3d at 1340 (noting that extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art are available sources to show what one of skill in the art understood disputed claim term to mean).

During the trial court proceedings, the district court heard expert testimony on the background of the technology and the customary meaning of technical claim terms to assist in the court's interpretation of terms such as "therapeutically effective amount." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F.Supp.2d 202, 230 (D. Mass. 2004) ("*Amgen III*"). However, Judge Young felt caught in the conundrum of requiring extrinsic evidence to help understand the meaning of claim terms, while mindful of the Federal Circuit's narrow approach toward reliance on extrinsic evidence in claim construction. *Amgen III*, 339 F.Supp.2d at 226-28 n.23 ("How does a Court decipher the

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of whether there is a § 102(b) bar are reviewed under clearly erroneous standard); *Dippin' Dots Inc. v. Mosey*, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (factual determinations underlying legal conclusion of inequitable conduct are reviewed for clear error).

plain and customary meaning of a term as understood by one skilled in the art without resorting to extrinsic evidence about how one skilled in the art would construe the term?"),[4] *see also id.* at 229 n.25; *id.* at 231 n.28; *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1318 (Fed. Cir. 2006) ("*Amgen IV*") (Michel, C.J., dissenting-in-part) (noting extensive trial court proceedings, the court's creative step of employing a technical advisor on the underlying technology, extensive time spent rendering revised claim constructions and making extensive findings of fact and conclusions of law).

To eliminate this dilemma faced by trial courts, the SDIPLA urges the granting of *certiorari* and a holding that the District Court should find the facts necessary for claim construction, including the definition for one of ordinary skill in the art and the customary meaning of claim terms. Further, the holding in *Cybor*, that all aspects of claim construction are reviewed *de novo*, should be reversed.

B. THE FEDERAL CIRCUIT'S APPLICATION OF THE "FLEXIBLE RULE" GOVERNING REBUTTAL OF THE SURRENDER OF EQUIVALENTS RESURRECTS THE ABSOLUTE BAR REJECTED IN *FESTO*

In *Festo*, the Court re-affirmed that although the doctrine of equivalents renders the scope of patents less certain, such uncertainty is the necessary price for "ensuring the appropriate incentives for innovation." *Festo*, 535 U.S. at 723; *see also Warner-Jenkinson Co. v. Hilton*

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[4] *Cybor*, 138 F.3d at 1481 (Rader, J., dissenting) ("Surely the better view is to encourage judicial access to scientific evidence and findings based thereon. The ultimate beneficiary would be the parties, for the courts would be less restricted in the search for the correct and just result in patent cases.").

Davis Chem. Co., 520 U.S. 17, 29 (1997). Accordingly, although a narrowing amendment made for purposes of patentability may give rise to an estoppel that surrenders the territory between the original claim limitation and the amended claim limitation, *Festo*, 535 U.S. at 736, in some cases, "the amendment cannot reasonably be viewed as surrendering a particular equivalent," *id.* at 725.

The patentee may rebut the presumption that estoppel bars a claim of equivalence by showing "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 535 U.S. at 741. More specifically, there are three circumstances when an amendment cannot reasonably be viewed as surrender:

> The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

Id. at 740-741.

Absent this opportunity to rebut the presumption of surrender of equivalents, a patentee who amended claims during prosecution could not exclude copiers making insubstantial changes to an invention. The value of patents would be substantially diminished, and innovation would be negatively impacted. Accordingly, "[t]he Court has consistently applied the doctrine in a flexible way, considering what equivalents were surrendered during a patent's prosecution, rather than imposing a complete bar

that resorts to the very literalism the equivalents rule is designed to overcome." *Festo*, 535 U.S. at 724.

This flexible approach toward the doctrine of equivalents recognized that a patentee should not be unduly punished for agreeing to narrow a claim during prosecution. *See Festo*, 535 U.S. at 738. An amended claim does not become "so perfect in its description that no one could device an equivalent . . . [t]he narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is." *Id.* "By amending the application, the inventor is deemed to concede that the patent does not extend as far as the original claim, *not that the amended claim is so perfect in its description that no one could devise an equivalent.*" *Id.* at 724 (emphasis added).

Following this Court's remand in *Festo*, Judge Newman cautioned that the Federal Circuit's "generous interpretation of the scope of surrender, and stinginess toward its rebuttal" in applying this Court's *Festo* standard for rebuttal created a framework that "few patentees can survive." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1385 (Fed. Cir. 2003) (Newman, J., concurring-in-part and dissenting-in-part). Judge Newman's forewarnings did not ring hollow. Indeed, in the five years since this Court decided *Festo*, only two patentees on appeal have successfully overcome the presumption of surrender of equivalents, invoking the "tangential relationship" test. *See Insituform Techs Inc. v. CAT Contracting Inc.*, 385 F.3d 1360, 1368 (Fed. Cir. 2004); *Primos Inc. v. Hunter's Specialties Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006). On appeal, no patentee has ever successfully rebutted the presumption based on foreseeability or "some other reason."

Even the one possible avenue for successfully rebutting the presumption of surrender has recently been further constrained by the Federal Circuit's cautioning

that "the tangential rebuttal principle remains very narrow." *Cross Med. Prods. v. Medtronic Sofamor Danek Inc.*, ___ F.3d ___, 82 USPQ2d 1065, 1075 (Fed. Cir. 2007) (Rader, J., concurring). The time is ripe for this Court to ensure that the Federal Circuit allows a patentee to "capture every nuance" of her invention by correctly applying its *Festo* standard to rebut the presumption of surrender of equivalents.

1. The Federal Circuit Applied the Wrong Test for Doctrine of Equivalents in *Amgen IV*

Although the Federal Circuit in *Amgen IV* purported to apply the Court's "tangential relation" test in determining whether Amgen successfully rebutted the *Festo* presumption of surrender of equivalents, it reformulated the test and made it impossible for the patentee to survive the analysis.

Judge Young correctly applied this Court's *Festo* test in determining that Amgen's amendment restricting the literal scope of the '080 patent to EPO having the complete amino acid sequence shown in Figure 6, was added only for purposes of limiting the '080 patent to human EPO products, and thus the amendment was no more than tangentially related to TKT's 165-amino acid equivalent. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 287 F.Supp.2d 126, 154 (D. Mass. 2003) ("*Amgen III (DOE)*"). The Federal Circuit, in overturning Judge Young's legally sound conclusion, however, applied its own novel standard: "the 165-amino acid equivalent is only tangential if the patentee's reason for limiting the '080 patent to EPO with 166 amino acids was unrelated to distinguishing the scope of the '080 patent from the scope of the '933 patent." *Amgen IV*, 457 F.3d at 1314. Thus, the Federal Circuit erroneously analyzed whether the amendment "for limiting the '080 patent to EPO with 166 amino acids" was made to "distinguish[]

the scope of the '080 patent from the scope of the '933 patent," *i.e.*, to overcome a double patenting rejection in light of the '933 patent. Essentially, the Federal Circuit stated that an equivalent is only tangential if the rationale for the amendment is unrelated to patentability.

However, as this Court enunciated, if the rationale for an amendment is unrelated to patentability, the presumption of prosecution history estoppel does not even apply. The Federal Circuit failed to properly consider whether "the rationale underlying the amendment" was tangentially related to the 165 amino acid equivalent, as required by a proper *Festo* analysis. *See Festo*, 535 U.S. at 736. For this reason, the Federal Circuit's ruling cannot stand.

2. The Determination of Whether the *Festo* Presumption Is Rebutted Is Based on Factual Underpinnings and Should Be Subject to Deferential Review

Like claim construction, a determination of whether a patentee has successfully rebutted the presumption of prosecution history estoppel is based on factual underpinnings that should be subject to deference on appellate review.

The Federal Circuit has held that the issue of whether a patentee has successfully rebutted a *Festo* presumption of surrender of equivalents is a question of law to be reviewed *de novo*. *Amgen IV*, 457 F.3d at 1312; *see, e.g., Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357 (Fed. Cir. 2006); *Rhodia Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *Ranbaxy Pharms., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1240 (Fed. Cir. 2003). However, in setting forth the general standard governing rebuttal of the presumption of surrender, the Federal Circuit recognized that factual findings may underlie this determination: "[b]y its very nature, objective unforeseeability depends on underlying factual issues relating to,

for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. Therefore, in determining whether an alleged equivalent would have been unforeseeable, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries." *Festo*, 344 F.3d at 1369.

The Federal Circuit further stated that whether an amendment narrowed a claim for reasons tangential to the equivalent should be discernible "from the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record." *Festo*, 344 F.3d at 1370. Likewise, determination of rebuttal for "some other reason" should be limited to the prosecution history record. *Id.*

To the extent the Federal Circuit has asserted that the test for a "tangential relation" or "other reasons" rebutting the surrender of equivalents is based solely on the intrinsic evidence, this is not the case. This Court has noted that a determination of surrender of equivalents requires an analysis of extrinsic evidence. *See Festo*, 535 U.S. at 741 ("the patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent"). Judge Newman has also cautioned that the "tangential relation" and "some other reasons" tests are based on underlying fact:

> [T]he factors relevant to determination of tangential relation are unlikely to reside in the prosecution record, for unrelated subject matter or unknown equivalents are unlikely to have been discussed by either the examiner or the applicant. The issue of "tangentialness" may require consideration of how the reason for an amendment affected the patentee's view that certain technology was extraneous. The prosecution

> record rarely discusses devices that are not prior art.

Festo, 344 F.3d at 1384 (Newman, J., concurring in part and dissenting in part). Further, "[l]ike tangentialness, if some other reason arises that relates to the alleged equivalent, evidence would be more likely to reside outside of the prosecution record than within it." *Id.* at 1385.[5] Thus, like foreseeability, they should be established based on underlying questions of fact, and not law. *Id.* at 1383.

Appellate review should afford the trial court significant deference in factual findings underlying the determination of rebuttal of the surrender of equivalents. Continuing to indulge in the fiction that rebuttal is a question of law subject to *de novo* review not only leads to uncertainty and unpredictability about the finality of judgments at trial, but also prevents a district court from taking "full advantage of its unique ability to evaluate the relevant technology." Marc D. Sharp, *Festo X: The Complete Bar by Another Name?* 19 BERKELEY TECH. L.J. 111, 123-24 (2004).

IV. CONCLUSION

The SDIPLA therefore respectfully urges the Court to grant *certiorari* and hold that the District Court should find the facts necessary for claim construction. The holding in *Cybor*, that all aspects of claim construction are reviewed *de novo*, should be reversed. Moreover, the Court should reverse the Federal Circuit's ruling on the Doctrine of Equivalents, and direct the Federal Circuit to apply the

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[5] Judge Young also noted that an objective analysis as to whether "some other reason" reasonably prevented the patentee from describing the alleged equivalent may depend on underlying factual issues relating to the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. *Amgen III (DOE)*, 287 F.Supp.2d at 155.

correct test for whether the patentee rebutted the presumption of the surrender of equivalents. The SDIPLA further urges that the Court order that the Federal Circuit review with deference the fact findings underlying the district court's determination of rebuttal.

Respectfully submitted,

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